

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks are respectfully requested.

Pursuant to the Official Action mailed July 3, 2002, Groups II and III have been rejoined by the Examiner. The Examiner's rejoining of Groups II and III (claims 3-6) is greatly appreciated. Claims 3-6 are pending for consideration. By the present response claims 3-6 have been canceled without prejudice to or disclaimer of the subject matter therein. New independent claim 19 and dependent claims 20-22 have been added. No new matter has been added. Additionally, the abstract of the claimed invention has been replaced.

Priority:

The Examiner's acknowledgment of Applicants' claim for foreign priority is appreciated. However, the Examiner has noted that Applicants have not filed a certified copy of the 2000-71,655 Japanese application (filed on March 15, 2000). The certified copy of the above-mentioned Japanese priority application is filed herewith.

Specification Objections:

The Examiner has objected to the abstract of the application for allegedly incorporating legal phraseology used in patent claims, such as "means" and "said." Without conceding to the Examiner's objection and in order to expedite the prosecution of

the subject application, Applicants have replaced the abstract to omit the objected to language. A favorable reconsideration of the abstract is respectfully requested.

Claim Objections:

The Examiner has objected to claims 3 and 4 for allegedly depending from a claim to a non-elected invention. Claims 3 and 4 have been canceled without prejudice or disclaimer and have been replaced by claims 19 and 20. This objection as it relates to the canceled claims 3 and 4 is, therefore, moot.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph:

The Examiner has rejected claims 3-6 and claim 1 to the extent that its limitations are incorporated into claims 3 and 4, under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 3-6 have been canceled without prejudice or disclaimer and have been replaced by claims 19-22. This rejection to the extent that it relates to claims 3-6 is therefore moot.

To the extent that canceled claim 5 relates to the new claim 21, Applicants disagree with the Examiner's rejection of canceled claim 5 as allegedly being indefinite for not reciting conditions of hybridization. § 2173.02 of the MPEP states:

Definiteness of claim language must be analyzed, not in vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Applicants contend that the specification of the subject application, by form of Examples, at page 6, paragraphs [0013] and [0014], disclose at least one technique of hybridization which may be utilized in the claimed invention. In these Examples Applicants disclose, in detail, hybridization parameters including the solutions used, temperature ranges and other required conditions to achieve the means of the claimed invention. Further, Applicants contend that hybridization techniques are well-known, and are merely routine to a persons possessing the ordinary level of skill in the pertinent art. The specification need not teach what is known in the art (e.g. stringent hybridization conditions). In fact, the Federal Circuit has stated that a person need not teach, and preferably omits, what is well-known in the art. *See Hybritech, Inc. v. Monoclonal Antibodies, Ind.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). From the foregoing we conclude that the language of the claims recited in the subject application regarding hybridization conditions is definite. Withdrawal of this rejection is respectfully moot.

Claims Rejected Under 35 U.S.C. § 101 and § 112, First Paragraph:

The Examiner has rejected claims 3-6 under 35 U.S.C. § 101 for allegedly claiming an invention directed to non-statutory subject matter. The Examiner alleges that the claims are drawn to a gene and thus drawn to a product of nature.

Claims 3-6 have been canceled without prejudice or disclaimer. Therefore, this rejection is moot.

The Examiner has further rejected claims 3-6 for allegedly claiming an invention not supported by either a specific or a well-established utility and lacking substantial utility.

Claims 3-6 have been canceled without prejudice or disclaimer. Therefore, this rejection is moot.

However, as to the extent that this rejection relates to the new claims 19-22, Applicants disagree with the Examiner's allegations based on the following arguments and Tamura et al.¹

Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

See MPEP § 2107-II.

"An invention has a well established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g. properties or application of a product or process) and (ii) the utility is specific, substantial, and credible." See MPEP § 2107-II.

Applicants contend that the Examiner has failed to establish a *prima facie* showing of no specific and substantial credible utility. The Examiner has neither provided scientific documentary evidence or has she explained specifically the scientific basis for her factual conclusion.

Even if the Examiner has satisfied the *prima facie* requirements for proving non-utility, Applicants submit that the claimed invention simply possesses specific and

¹ Takashi Tamura, Kojiro Hara, Yube Yamaguchi, Nozomu Koizumi and Hiroshi Sano, "Osmo-stress tolerance of tobacco expressing *NtC7*," scheduled to be published in *Plant Physiology*).

substantial credible utility and this utility is immediately apparent to one of ordinary skilled in the art. By virtue of the information disclosed in the specification and especially in the Examples, Applicants clearly convey the usefulness of the claimed invention to one of ordinary skill in the art. Applicants respectfully direct the Examiner's attention to paragraphs [0040] and [0041] of the specification which explain the method of measuring the resistance of a transgenic plant, carrying the claimed isolated DNA molecule, against environmental stress. Environmental stresses, in general, are ordinary phenomena with which at least all farmers must combat to produce healthy and abundant crops. This exemplary use of the claimed invention is certainly neither insubstantial or non-specific. This exemplary utility of the claimed invention is also credible from the perspective of one of ordinary skill in the art in view of the above-mentioned Examples and especially from the specification, paragraphs [0040] and [0041].

One specific example of an environmental stress is osmotic stress. The effects of osmotic stress on plants are illustrated by Tamura et al. This scientific article has been accepted by the Plant Physiology journal and will be published within the next several weeks. One of the authors of the subject application is also the corresponding author of this above-mentioned scientific article. Applicants contend that Tamura et al. clearly illustrates the utility of the claimed invention. Figure 7 of this scientific article shows effects of osmotic and salt stresses on transgenic tobacco seedlings. As shown in Figure 7B, the transgenic seedlings expressing NtC7 (C7 of this invention) exhibit clear resistance to osmotic stress caused by mannitol. Also, Figure 8 shows effects of osmotic stress on tobacco mature leaves. These leaves are treated with 500mM mannitol solution and

allowed to recover from wilting. Upon treatment for 12hr, leaves exhibited severe necrosis all over the surface and ultimately died after 2 days. These results were compared to the results attained from treatment of transgenic plants for 12hr, and their recovery from wilting. As shown in Figure 8B, leaves from transgenic plants expressing NtC7 (#1, #6 and #53, refer to blotting data of Figure 7B) rapidly recovered from mannitol treatment. Leaves not expressing NtC7 (#9 and #40) did not recover.

Applicants contend that the results shown in this scientific article and the evidence disclosed throughout the subject application clearly support utility of the claimed isolated DNA. It is clear from the foregoing that the transformed plants of the claimed invention exhibit resistance to at least osmotic pressures.

Withdrawal of this rejection in light of the forgoing arguments and new claims is respectfully requested.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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